

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC.)	
and SCR PHARMATOP,)	
)	
Plaintiffs,)	
v.)	C.A. No. 11-733 (LPS)
)	
EXELA PHARMA SCIENCES, LLC; EXELA)	PUBLIC VERSION
PHARMSCI, INC.; and EXELA HOLDINGS,)	
INC.;)	
)	
Defendants.)	

**PUBLIC VERSION OF EXHIBITS C AND M TO
REDACTED [PROPOSED] FINAL PRETRIAL ORDER**

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April 23, 2013

EXHIBIT C

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DEFENDANTS' STATEMENT OF ISSUES OF FACT TO BE LITIGATED AT TRIAL¹

Defendants' identification of issues of fact that remain to be litigated is based in part on Defendants' current understanding of the arguments that Plaintiffs are likely to make in attempting to prove allegations of infringement and defend against allegations of invalidity, based on the pleadings and discovery in this action to date. To the extent that Plaintiffs intend or attempt to introduce different or additional facts to meet their burden of proof, Defendants reserve their right to contest those facts, and to present any and all rebuttal evidence in response to those facts.

To the extent that Defendants' statement of issues of law set forth in Exhibit E contains issues of fact, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this Exhibit as an issue of fact is more appropriately considered an issue of law, Defendants incorporate such issues by reference into its statement of issues of law. By including a fact herein, Defendants do not assume the burden of proof or production with regard to that fact.

I. NONINFRINGEMENT

1. Whether Plaintiffs have shown by a preponderance of the evidence that claims 1-5, 9-10, 12, and 16-18 of the '222 patent (collectively, the "asserted claims of the '222 patent") and claims 1, 3, 4, 8, 9, and 19 of the '218 patent (collectively, the "asserted claims of the '218 patent") would be infringed by the acetaminophen formulation that is the subject of Exela's ANDA No. 203092 ("Exela's ANDA product") or by Exela's process of making its ANDA product ("Exela's ANDA process"), either literally or under the doctrine of equivalents.

2. Whether Plaintiffs have shown by a preponderance of the evidence that Exela's ANDA product and/or Exela's ANDA process meet each and every claim limitation of the

¹ Defendants reserve the right to amend and/or supplement Defendants' Statement of Contested Facts based on, *inter alia*, the continuing discovery in this case and the resolution of any pending dispute currently before the Court

Asserted Claims of the Patents-In-Suit, as those claim terms have been construed by the Court, either literally or under the doctrine of equivalents.

II. INVALIDITY

A. Anticipation

3. Whether claims 1-4, and 16-18 of the '222 patent and claims 1, 3, 4, and 19 of the '218 patent are invalid as anticipated under 35 U.S.C. § 102.

4. Whether Greek Patent Publication No. 871510 (Application Number G.P. 870101510) is prior art to the Patents-in-Suit under 35 U.S.C. § 102(b).

5. Whether Korean Patent No. 1993-0011994 is prior art to the Patents-in-Suit under 35 U.S.C. § 102(b).

6. Whether Greek Patent Publication No. 871510 discloses each and every element of claims 1-4, and 16 of the '222 patent, and therefore anticipates those claims.

7. Whether Korean Patent No. 1993-0011994 discloses each and every element of claims 1, 3, 4, 17, and 18 of the '222 patent, and therefore anticipates those claims.

8. Whether U.S. Patent No. 5,270,050 discloses each and every element of claims 1, 3, 16, and 17 of the '222 patent, and therefore anticipates those claims.

9. Whether the '222 patent discloses each and every element of claims 1, 3, 4, and 19 of the '218 patent, and therefore anticipates those claims.

B. Obviousness

10. Whether the Asserted Claims of the Patents-in-Suit are invalid as obvious under 35 U.S.C. § 103.

11. What was the scope and content of the prior art at the time the invention claimed by the '222 patent was made.

12. What are the differences, if any, between the invention claimed by the '222 patent and the prior art.

13. Whether the differences, if any, between the subject matter of the asserted claims of the '222 patent and the prior art are such that the subject matter as a whole would have been obvious prior to the asserted claims' effective filing date to a person having ordinary skill in the art to which the claimed invention pertains.

14. Whether a person of ordinary skill in the art would have been motivated to combine or modify the prior art references to arrive at the invention of the asserted claims of the '222 patent with a reasonable expectation of success.

15. Whether the asserted claims of the '222 patent are obvious in view of Greek Patent Publication No. 871510 or Korean Patent No. 1993-0011994 or U.S. Patent No. 5,270,050, alone or in combination with other prior art.

16. What was the scope and content of the prior art at the time the alleged invention claimed by the '218 patent was made.

17. What are the differences, if any, between the alleged inventions claimed by the '218 patent and the prior art.

18. Whether the differences, if any, between the subject matter of the asserted claims of the '218 patent and the prior art are such that the subject matter as a whole would have been obvious before the asserted claims' effective filing date to a person having ordinary skill in the art to which the claimed invention pertains.

19. Whether a person of ordinary skill in the art would have been motivated to combine or modify the prior art references to arrive at the invention of the asserted claims of the '218 patent with a reasonable expectation of success.

20. Whether the asserted claims of the '218 patent are obvious in view of the '222 patent, alone or in combination with other prior art.

21. To the extent that Plaintiffs raise any secondary considerations of nonobviousness, whether Plaintiffs have carried their burden of showing the existence of any

such secondary considerations and that they have a nexus to the Asserted Claims of the Patents-in-Suit.

C. Indefiniteness

22. Whether the asserted claims of the '222 patent are indefinite, and thus invalid under 35 U.S.C. § 112, ¶ 2, for failure to particularly point out and distinctly claim the subject matter therein.

23. Whether a person of ordinary skill in the art to which the '222 patent pertains would understand whether a given agent is “a buffering agent” as that term is used in the asserted claims of the '222 patent, and as construed by the Court.

III. EXCEPTIONAL CASE

24. Whether Plaintiffs have proven by clear and convincing evidence willful infringement.

25. Whether Plaintiffs lacked a good-faith basis for their infringement allegations so as to warrant an exceptional-case finding for purposes of 35 U.S.C. § 285.

IV. PLAINTIFFS' ADDITIONAL ALLEGATIONS RELATING TO DEFENDANTS' TESTING OF EXELA'S ANDA PROCESS FOR DEFENDANTS' EXPERT REPORT

26. Defendants contend that Plaintiffs' additional infringement allegations, namely whether Exela's testing of its ANDA process for Defendants' expert report falls outside of the 35 U.S.C. § 271(e)(1) safe harbor, do not constitute issues to be litigated at trial.²

² Defendants also dispute Plaintiffs' additional infringement allegations, which relate to Exela's testing of its ANDA process for Defendants' expert report, an activity that is protected by the 35 U.S.C. § 271(e)(1) safe harbor.

EXHIBIT M

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DEFENDANTS' STATEMENT OF INTENDED PROOF¹

Defendants submit the following brief statements of the primary matters that Defendants intend to prove in support of their counterclaims and defenses. The following statements are not exhaustive, and Defendants reserve the right to prove any matters identified in the pleadings, in interrogatory and other discovery responses, in expert reports, and in the accompanying statements of the factual and legal issues to be litigated at trial. Defendants may also provide additional proof to rebut any proof offered by Plaintiffs before and during trial, in response to rulings by the Court, or for other good cause.

I. NONINFRINGEMENT

Plaintiffs bear the burden of proving infringement by a preponderance of the evidence. To the extent that Plaintiffs purport to show that any of claims 1-5, 9-10, 12, and 16-18 of the '222 patent and claims 1, 3, 4, 8, 9, and 19 of the '218 patent (collectively, the "Asserted Claims") would be infringed by the acetaminophen formulation that is the subject of Exela's ANDA No. 203092 ("Exela's ANDA product") and/or by Exela's process of making its ANDA formulation ("Exela's ANDA process"), either literally or under the doctrine of equivalents, Defendants intend to directly rebut that showing, as explained in more detail below.

A. The '222 Patent

Claims 1-5, 9-10, 12, and 16-18 of the '222 patent (the "asserted claims of the '222 patent") each contain the claim element "a buffering agent," either directly or by dependency. Defendants intend to present evidence showing that Exela's ANDA product does not contain "a buffering agent," either literally or under the doctrine of equivalents.

¹ Defendants reserve the right to amend and/or supplement Defendants' Statement of Intended Proof based on Plaintiffs' Statement of Intended Proof, which Plaintiffs have not yet served on Defendants. Defendants also reserve the right to amend and/or supplement Defendants' Statement of Intended Proof based on, *inter alia*, the continuing discovery in this case and the resolution of any pending dispute currently before the Court.

B. The '218 Patent

Claims 1, 3, 4, 8, 9, and 19 of the '218 patent (the “asserted claims of the '218 patent”) each contain the claim term “deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm.” Defendants intend to present evidence showing that Exela’s ANDA process does not meet the claim limitations “deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm,” either literally or under the doctrine of equivalents.

The asserted claims of the '218 patent each contain the claim term “optionally the deoxygenation of the solution is completed by addition of an antioxidant.” Defendants intend to present evidence showing that Exela’s ANDA process does not meet the claim limitation “optionally the deoxygenation of the solution is completed by addition of an antioxidant,” either literally or under the doctrine of equivalents.

The asserted claims of the '218 patent each contain the claim term “the oxygen content of the aqueous solution is below 2 ppm.” Defendants intend to present evidence showing that Exela’s ANDA process does not meet the claim limitation “the oxygen content of the aqueous solution is below 2 ppm,” either literally or under the doctrine of equivalents.

Claim 19 of the '218 patent claims “an injectable aqueous solution” that is “preserved by the method of claim 1.” Defendants intend to present evidence showing that Exela’s ANDA product does not meet the claim limitation “preserved by the method of claim 1,” either literally or under the doctrine of equivalents.

II. INVALIDITY

As explained in more detail below, Defendants intend to prove by clear and convincing evidence that all of the Asserted Claim are invalid as anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103. Defendants also intend to prove by clear and convincing evidence that all of the asserted claims of the '222 patent are invalid under 35 U.S.C. § 112, ¶ 2.

A. Anticipation

1. The '222 Patent

Defendants intend to prove by clear and convincing evidence that claims 1-4, and 16-18 of the '222 patent are invalid under 35 U.S.C. § 102(b) because they are anticipated by the prior art. Specifically, Defendants intend to prove:

- Greek Patent Publication No. 871510 is prior art to the Patents-in-Suit.
- Greek Patent Publication No. 871510 discloses each and every element of claims 1-4, and 16 of the '222 patent, and therefore anticipates each of those claims.
- Korean Patent No. 1993-0011994 is prior art to the Patents-in-Suit.
- Korean Patent No. 1993-0011994 discloses each and every element of claims 1, 3, 4, 17, and 18 of the '222 patent, and therefore anticipates each of those claims.
- U.S. Patent No. 5,270,050 (the “ '050 patent”) discloses each and every element of claims 1, 3, 16, and 17 of the '222 patent, and therefore anticipates those claims.

2. The '218 Patent

Defendants intend to prove by clear and convincing evidence that claims 1, 3, 4, and 19 of the '218 patent are invalid under 35 U.S.C. § 102(b) because they are anticipated by the prior art. Specifically, Defendants intend to prove that the prior art '222 patent discloses each and every element of claims 1, 3, 4, and 19 of the '218 patent, either expressly or inherently, and therefore anticipates each of those claims.

B. Obviousness

1. The '222 Patent

Defendants intend to prove by clear and convincing evidence that all of the asserted claims of the '222 patent would have been obvious in view of the prior art, and therefore are invalid under 35 U.S.C. § 103(a). Defendants expect to rely on at least the following prior art references:

- Greek Patent Publication No. 871510
- Korean Patent No. 1993-0011994
- U.S. Patent No. 5,270,050
- Connors et al., Chemical Stability of Pharmaceuticals, A Handbook for Pharmacists, Chapter 5, (1979)
- European Patent Publication No. EP 0037043
- U.S. Patent No. 3,161,310
- A. Palmieri, III et al., "Utilization of Deaeration Via Gas Permeation and Oxidative Stabilization of Pyrogallol," Drug Development Communications 2(2):171-192 (1976) ("Palmieri 1976")
- A. Palmieri, III, "Effect of Dissolved Oxygen Levels on Oxidative Degradation of Pyrogallol," Journal of Pharmaceutical Sciences, Vol. 67, No. 9 (1978) ("Palmieri 1978")
- Parrott, Pharmaceutical Technology, Fundamental Pharmaceutics (1970)
- Penin I.R. et al., Preparation of an Injectable Form of Paracetamol, 4 Journal A.E.F.H XI 249-54 (1987)
- K.T. Koshy and J.L. Lach, "Stability of aqueous solutions of N-acetyl-p-aminophenol," J. Pharmaceutical Sciences 113-18 (1961)

Defendants intend to prove that the asserted claims of the '222 patent would have been obvious to a person having ordinary skill in the art on the following independent grounds: (1) based on Greek Patent Publication No. 871510, alone or in combination with other prior art; (2)

based on Korean Patent No. 1993-0011994, alone or in combination with other prior art; and (3) based on U.S. Patent No. 5,270,050, alone or in combination with other prior art. For these independent grounds, Defendants expect to present evidence that a person of ordinary skill in the art would have had reason to modify or combine the prior art references to arrive at the invention of the asserted claims of the '222 patent with a reasonable expectation of success.

To the extent that Plaintiffs purport to show any secondary considerations of nonobviousness in support of their contention that the Asserted Claims are not obvious, Defendants intend to directly rebut that showing with proof that such secondary considerations do not exist and/or that there is no nexus between such secondary considerations and the asserted claims of the '222 patent.

2. The '218 Patent

Defendants intend to prove by clear and convincing evidence that all of the asserted claims of the '218 patent are invalid as obvious under 35 U.S.C. § 103(a) in view of the prior art. Defendants expect to rely on the '222 patent as primary prior art reference. Defendants also expect to rely on Palmieri 1976, Palmieri 1978, U.S. Patent No. 4,259,360, DD 279405, and/or EP 1094802 as prior art.

Defendants intend to prove that the asserted claims of the '218 patent would have been obvious to a person having ordinary skill in the art in view of the '222 patent along with the knowledge of a person having ordinary skill in the art, as informed by various prior art references. Defendants expect to present evidence that a person of ordinary skill in the art would have had reason to modify or combine the prior art to arrive at the invention of the asserted claims of the '218 patent with a reasonable expectation of success.

To the extent that Plaintiffs purport to show any secondary considerations of nonobviousness in support of their contention that the asserted claims of the '218 patent are not

obvious, Defendants intend to directly rebut that showing with proof that such secondary considerations do not exist and/or that there is no nexus between such secondary considerations and the asserted claims of the '218 patent.

C. Indefiniteness

Defendants intend to prove by clear and convincing evidence that all of the asserted claims of the '222 patent are indefinite, and thus invalid under 35 U.S.C. § 112, ¶ 2, for failure to particularly point out and distinctly claim the subject matter therein. Specifically, Defendants intend to prove that a person of ordinary skill would not understand whether a given agent is “a buffering agent” according to the asserted claims of the '222 patent.

D. Exceptional Case

To the extent that Plaintiffs purport to show willful infringement, Defendants intend to directly rebut by showing that they did not willfully infringe any of the Asserted Claims and that Plaintiffs have not met their burden of proving by clear and convincing evidence that this is an exceptional case.

Defendants also intend to prove by clear and convincing evidence that Plaintiffs lacked a good-faith basis for their infringement allegations so as to warrant an exceptional case finding for purposes of 35 U.S.C. § 285.